

## **Zuberitamab (Anruixi®), the first domestically developed anti-CD20 antibody as a Class I innovative drug from BioRay Pharmaceutical, has been approved for marketing in China**

Recently, BioRay Pharmaceutical Co., Ltd. (hereinafter referred to as "Bioray") announced that its independently developed Class I innovative therapeutic biological product, Zuberitamab Injection (trade name: Anruixi®), indicated for the treatment of CD20-positive diffuse large B-cell lymphoma (DLBCL), was officially approved for marketing by the National Medical Products Administration (NMPA).

In preclinical studies, Anruixi® showed stronger antibody-dependent cell-mediated cytotoxicity (ADCC), a larger volume of distribution at steady state, and more sustained clearance of B cells, demonstrating better efficacy compared to other products. Positive results were observed in a randomized, double-blind, active-controlled phase III clinical trial of Anruixi®, conducted in 43 study sites nationwide with 487 subjects enrolled. In the head-to-head study with Rituximab, the overall response rate of Anruixi® + CHOP was not inferior to that of R-CHOP in patients with early-stage DLBCL, and it had a significantly higher complete response rate vs. R-CHOP. In terms of long-term survival benefits, the Anruixi® group achieved better 1-year, 2-year, and 3-year PFS and OS rates compared with the Rituximab group.

As the first domestically developed Class I anti-CD20 drug in China, Anruixi® will become BioRay's next major product following Anruize®. Additionally, clinical research is being conducted to explore the use of Anruixi® in the field of autoimmune diseases, such as primary immune thrombocytopenia (ITP).

"As the company's sixth product on the market and its first new drug in the field of tumor immunology, we are particularly grateful for the tremendous efforts made by the clinical researchers who participated in the product's clinical study, our partners, and our colleagues at Bioray," said Dr. Haibin Wang, CEO of Bioray. "In the future, Bioray will continue to focus on the field of immunology and the unmet medical needs, providing more clinical treatment options, and bringing more medical solutions to patients."

### **ABOUT BIORAY**

BioRay is a pioneer in China's biopharmaceutical industry focusing on immune-mediated diseases. Its extensive autoimmune and oncology portfolio includes six marketed products and over 10 clinical-stage drug candidates. Operating a fully integrated platform with end-to-end capabilities across drug discovery, clinical development, manufacturing, and commercialization, BioRay has over 1,700 employees globally, with main sites in Taizhou, Hangzhou, Shanghai, and San Diego.

For more information about BioRay, please visit the company website: [www.bioraypharm.com/en/](http://www.bioraypharm.com/en/)

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